UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,388	11/27/2001	Alan P. Carpenter, JR.	PH-7201	1791

23914 7590 03/11/2003

STEPHEN B. DAVIS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER
JONES, DAMERON

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,388	CARPENTER,, ALAN P.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION INTO GROUPS

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 23-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target is comprises the sequence, cyclo (Arg-Gly-Asp-Tyr-...Val) (see for example, claim 20, first compound on page 245), classified in class 424, subclass 1.69.

II. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo(Arg-Val-Tyr-Asp-...Gly) (see for example, claim 20, second compound on page 245), classified in class 424, subclass 1.69.

III. Claims 1-27, and 29-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo (Arg-Gly-Asp-Phe-Lys) (see for example, claim 20, second compound on page 246), classified in class 424, subclass 1.69.

IV. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo(Arg-Gly-Asp-Tyr-Lys) (see for example, claim 20, third compound on page 246), classified in class 424, subclass 1.69.

V. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, Phe-Glu(cyclo(Lys-Arg-Gly-Asp-Phe)-cyclo (Lys-Arg-Gly-Asp-Nal) (see for example, claim 20, fourth compound on page 246), classified in class 424, subclass 1.69.

VI. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo (Arg-Gly-Asp-Nal-Lys) (see for example, claim 20, fifth compound on page 246), classified in class 424, subclass 1.69.

VII. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, Glu (cyclo(Lys-Arg-Gly-Asp-Nal)-cyclo(Lys-Arg-Gly-Asp-Nal) (see for example, claim 20, sixth compound on page 246), classified in class 424, subclass 1.69.

VIII. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, Glu (O-cyclo (Lys-Arg-Gly-Asp-Phe)-O-cyclo (Lys-Arg-Gly-Asp-Phe) (see for example, claim 20, eighth compound on page 246), classified in class 424, subclass 1.69.

IX. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target

comprises the amino acid sequence, Glu(O-cyclo(Tyr-aminopropyl)-Val-Arg-Gly-Asp)-O-cyclo(Tyr(3-aminopropyl)-Val-Arg-Gly-Asp) (see for example, claim 20, compound bridging pages 246-247), classified in class 424, subclass 1.69.

X. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo(Arg-Gly-Asp-Lys(N-5-carbonyl-2-pyridinyl-diazenido)-Val (see for example, claim 20, first complete compound listed on page 247 (lines 4-5)), classified in class 424, subclass 1.69.

XI. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo(Lys-5-carbonyl-2-pyridinyl-diazendio-Phe-Asp-Gly-Arg (see for example, claim 20, compound on lines 7-8 on page 247), classified in class 424, subclass 1.69.

XII. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, 5-carbonyl-2-pyridinyl-diazenido-Glu-cyclo(Lys-Phe-Asp-Gly-Arg)-cyclo(Lys-Phe-Asp-Gly-Arg) (see for example, claim 20, compound listed in lines 10-12 on page 247), classified in class 424, subclass 1.69.

XIII. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo(Phe-Lys-5-carbonyl-2-pyridinyl-diazenido-Asp-Gly-Arg (see for example, claim 20, compound listed in lines 14-15 on page 247), classified in class 424, subclass 1.69.

XIV. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo(N-Me-Arg-Gly-Asp-ATA-Lys(N-5-carbonyl-2-pyridinyl-diazenido) (see for example, claim 20, compound listed in lines 17-18 on page 247), classified in class 424, subclass 1.69.

XV. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, cyclo(Cit-Gly-Asp-Phe-Lys-5-carbonyl-2-pyridinyl-diazenido) (see for example, claim 20, compound listed in lines 20-21 on page 247), classified in class 424, subclass 1.69.

XVI. Claims 1-21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target comprises the amino acid sequence, Glu(cyclo-Lys-Arg-Gly-Asp-Phe)-cyclo(Lys-Arg-Gly-Asp-Phe) (see claim 22, first compound on page 248), classified in class 424, subclass 1.69.

XVII. Claims 1-19, 21-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the target

comprises the compound, Glu-cyclo(Arg-Gly-Asp-Phe-Lys)2-dodecane1,12-dione (see for example, claim 42, last compound on page 262), classified in class 424, subclass 1.69.

XVIII. Claims 1-19, 21, 23-27, 29-41, and 43-66, drawn to a method of imaging comprising administering a vitronectin receptor target wherein the vitronectin receptor target is not one encompassed in Groups I-XVII above, classified in class 424, subclass 1.69.

Note: Claims appearing in more than one group will be examined only to the extent that they read upon the elected invention.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are unrelated because a search of one vitronectin receptor targeting agent as set forth in the groups above would neither anticipate nor render obvious the sequences in the other groups, even though the use is the same. Furthermore, it should be noted that each peptide sequence represents a patentably distinct product with distinct physical and chemical properties. Hence, a search for more than one product (and uses thereof) would be burdensome since each agent

would require a separate search in combination with other components (e.g., a perfusing imaging agent).

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES FOR SEARCH PURPOSES

4. Claims 1-66 are disclose a plurality of disclosed patentably distinct species comprising vitronectin receptor targeted imaging agents and a perfusion imaging agent. In particular, possible vitronectin imaging agents may be those having the sequences as set forth in claim 20. Furthermore, possible perfusion agents include ultrasound, MRI, and radiolabeled perfusion agents. Applicant is respectfully requested to elect a single disclosed species, even though this requirement is traversed.

Note: Applicant is respectfully requested to elect a single disclosed species for search purposes. The species should include a perfusion imaging agent. However, if Group XIX is elected, Applicant is respectfully requested to identify the vitronectin receptor imaging agent and the perfusion imaging agent. In addition, it should be noted that if Group XIX is elected and a vitronectin agent is set forth, a group containing that specific agent will be generated.

5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

March 10, 2003